**Missing documents list MAA**

|  |
| --- |
| Concerned Product:  |
| Submission Type: |
| Art. 12 TPA |
|  | **Product type:** |
|  | [ ]  | New active substance |
|  | [ ]  | Known active substance |
| Art. 13 TPA |
| **Product type:** |
|  | [ ]  | New active substance |
|  | [ ]  | Known active substance |
| **Dossier available from one of those countries:** |
|  | [ ]  | Australia |
|  | [ ]  | EU and EFTA-countries |
|  | [ ]  | Japan |
|  | [ ]  | Canada |
|  | [ ]  | New-Zealand |
|  | [ ]  | Singapore |
|  | [ ]  | USA |

**Documents and information needed for Art. 12 submission in Switzerland**

|  |
| --- |
| Swiss Module 1 |
|  | **Available?** |  |
|  | **YES** | **NO** | **N/A** | **Comment** |
| 1.0 Cover Letter |  |  |  |  |
|  | If certain documents required are not submitted, this must be stated in the cover letter or in the Checklist, Formal Control, with the reason for the omission | [ ]  | [ ]  | [ ]  |  |
|  | Product name plus appropriate details if other product designations are used | [ ]  | [ ]  | [ ]  |  |
|  | Short presentation of the clinical trials conducted | [ ]  | [ ]  | [ ]  |  |
|  | Comment if specific requirements are foreseen for implementing the spontaneous recording of suspected adverse drug reactions in Switzerland | [ ]  | [ ]  | [ ]  |  |
| 1.2 Application for Marketing Authorisation and Variation |
| **1.2.1 Form Application for Authorisation / Variation Human Medicines** | [ ]  | [ ]  | [ ]  |  |
|  | Insight in the public evaluation report | [ ]  | [ ]  | [ ]  |  |
|  | Information exchange with partner authorities of the Consortium | [ ]  | [ ]  | [ ]  |  |
|  | Evidence of notification of the use of a genetic resource or related traditional knowledge in accordance with the Nagoya Ordinance | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.1 Form Full Declaration** | [ ]  | [ ]  | [ ]  |  |
|  | The composition of flavouring agents need to be stated, as those can be covered by the duty of declaration e.g. Vanillin | [ ]  | [ ]  | [ ]  |  |
|  | The information given in the form full declaration shall be reflected in the “composition” section of the information for professionals and patients as well as on the packaging material (see 1.3) | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.2 Form Manufacturer Information** | [ ]  | [ ]  | [ ]  |  |
|  | The form shall reflect the information from the dossier | [ ]  | [ ]  | [ ]  |  |
|  | Compare the addresses of the manufacturers stated in the dossier and the gmp certificate 🡪 preferable use the addresses from the gmp certificate | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.3 Form Status Marketing Authorisations Abroad** | [ ]  | [ ]  | [ ]  |  |
|  | Countries; date of authorisation/submission/withdrawal/suspension/refusal and trade name of authorised/submitted/withdrawn/suspended/refused products | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.8 Form Substances of Animal or Human Origin** | [ ]  | [ ]  | [ ]  |  |
|  | Country/ies of origin of the source animals used for the manufacturing | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.9 Form Pharmaceutical Information for Parenteral Preparations** | [ ]  | [ ]  | [ ]  |  |
|  | Use text form the information for professionals and refer to the corresponding m3 section. No inconsistencies shall occur. | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.14 Checklist Formal Control Application Authorisation Human Medicines** | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.18 Form Confirmation Regarding Substances from GMO** | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.19 Form DMF for First Authorisation / Variations** | [ ]  | [ ]  | [ ]  |  |
|  | Swissmedic must receive the DMF– including the form DMF for first authorisation/variation (parts A and B), Letter of Access and covering letter from the DMF holder – no earlier than eleven calendar days before and no later than three calendar days after it has received the application for first authorisation or a variation from the marketing authorisation holder. If the DMF was not received in time, a formal deficiency letter will be sent to the authorisation holder. | [ ]  | [ ]  | [ ]  |  |
| 1.2.3 Annexes – Documents on Drug Quality |
| **1.2.3.1 DMF Letter of Access** | [ ]  | [ ]  | [ ]  |  |
|  | Swiss specific DMF Letter of Access(see Guideline on Active Substance Master File Procedure Annex 2: <http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000698.jsp&mid=WC0b01ac0580028bfd>) | [ ]  | [ ]  | [ ]  |  |
| **1.2.3.2 Ph. Eur. Certificate of Suitability for Active Substance** | [ ]  | [ ]  | [ ]  |  |
|  | Current valid versions of the CEPs of the API manufacturers **with the company named in the declaration box**(EDQM Database: <https://extranet.edqm.eu/publications/recherches_CEP.shtml>) | [ ]  | [ ]  | [ ]  |  |
| **1.2.3.3 Ph. Eur. Certificate of Suitability for TSE** | [ ]  | [ ]  | [ ]  |  |
|  | Current valid versions of Ph. Eur. Certificate of Suitability of TSE(EDQM Database: <https://extranet.edqm.eu/publications/recherches_CEP.shtml>) | [ ]  | [ ]  | [ ]  |  |
| **1.2.4 Annexes - Manufacturing** |
| **1.2.4.1 GMP Certificate or Other GMP Documents** | [ ]  | [ ]  | [ ]  |  |
|  | Valid GMP certificates (not older than 3 years (inspection date)) from all third parties to be registered (API, finished product, packaging, quality control, batch release) which reflect the actual manufacturing step the concerned manufacturer performs(EUDRA GMP Database:<http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do>) | [ ]  | [ ]  | [ ]  |  |
| **1.2.4.2 Documentation Concerning Manufacturing Authorisation** | [ ]  | [ ]  | [ ]  |  |
|  | Valid manufacturers licenses (not older than 3 years (inspection date)) from all third parties to be registered (API, finished product, packaging, quality control, batch release)🡪 Be aware that the manufacturers licences do not reflect the actual manufacturing step the concerned manufacturer performs(EUDRA GMP Database:<http://eudragmdp.ema.europa.eu/inspections/mia/searchMIA.do>) | [ ]  | [ ]  | [ ]  |  |
| **1.2.4.3 Complete Manufacturing Information with Flow Chart** | [ ]  | [ ]  | [ ]  |  |
|  | This is only mandatory for parenteral products but can also be added in the manufacturers form for other products if needed | [ ]  | [ ]  | [ ]  |  |
| **1.2.4.4 Confirmation on GMP Conformity** | [ ]  | [ ]  | [ ]  |  |
|  | Audit reports from all third parties to be registered but at least for API and finished product | [ ]  | [ ]  | [ ]  |  |
| 1.3 Product Information and Packaging Material |
| **1.3.1 Information for Professionals** | [ ]  | [ ]  | [ ]  |  |
|  | Current valid MedDRA Terms used(MedDRA: <https://www.meddra.org/how-to-use/support-documentation>) | [ ]  | [ ]  | [ ]  |  |
|  | Current valid standard terms used(Standard Terms Database: <https://standardterms.edqm.eu/>) | [ ]  | [ ]  | [ ]  |  |
|  | Current valid requirements from the AMZV considered (declaration of excipients) | [ ]  | [ ]  | [ ]  |  |
|  | Current valid formatting specification for the AIPS upload considered | [ ]  | [ ]  | [ ]  |  |
|  | Current valid fix texts used that are required from Swissmedic | [ ]  | [ ]  | [ ]  |  |
| **1.3.2 Patient Information** | [ ]  | [ ]  | [ ]  |  |
|  | Consistent with Information for professionals | [ ]  | [ ]  | [ ]  |  |
|  | Current valid fix texts used that are required from Swissmedic |  |  |  |  |
| **1.3.3 Packaging Information** | [ ]  | [ ]  | [ ]  |  |
|  | Consistent with Information for professionals regarding information on storage condition and excipients that require declaration | [ ]  | [ ]  | [ ]  |  |
|  | Mock-ups available to reflect arrangement, size and colour of text and graphics | [ ]  | [ ]  | [ ]  |  |
| 1.4 Information About the expert |
| **1.4.1 Quality** | [ ]  | [ ]  | [ ]  |  |
|  | Current signed version available | [ ]  | [ ]  | [ ]  |  |
| **1.4.2 Nonclinical** | [ ]  | [ ]  | [ ]  |  |
|  | Current signed version available | [ ]  | [ ]  | [ ]  |  |
| **1.4.3 Clinical** | [ ]  | [ ]  | [ ]  |  |
|  | Current signed version available | [ ]  | [ ]  | [ ]  |  |
| 1.6 Environmental Risk Assessment |
| **1.6.1 Non-GMO (statement)** | [ ]  | [ ]  | [ ]  |  |
| **1.6.2 GMO** | [ ]  | [ ]  | [ ]  |  |
|  | Consider EMA Guideline “Environmental Risk Assessments for Medicinal Products Containing, Or Consisting Of, Genetically Modified Organisms (GMOS)(<http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000953.jsp&mid=WC0b01ac0580a4aa6a>) | [ ]  | [ ]  | [ ]  |  |
| **1.8 Information Relating to Pharmacovigilance** | [ ]  | [ ]  | [ ]  |  |
| **1.8.1 Pharmacovigilance System** | [ ]  | [ ]  | [ ]  |  |
|  | Consider EMA Guideline “Guideline on good pharmacovigilance practices”(<http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c>) | [ ]  | [ ]  | [ ]  |  |
| **1.8.2 Risk Management System** | [ ]  | [ ]  | [ ]  |  |
|  | Consider EMA Guideline “Guidance on the format of the risk management plan (RMP) in the EU”(<http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000360.jsp&mid=WC0b01ac0580b91135>) | [ ]  | [ ]  | [ ]  |  |

**Additional/Separate documents and information needed for Art. 13 submission in Switzerland**

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| Swiss Module 1 |
|  | **Available?** |  |
|  | **YES** | **NO** | **N/A** | **Comment** |
| **1.2.2.15 Checklist Formal Control Application Authorisation Human Medicines Art.13** | [ ]  | [ ]  | [ ]  |  |
|  |  | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.20 Form Information Relating to Quality for Applications under Art. 13** | [ ]  | [ ]  | [ ]  |  |
|  | Details regarding to the DMF: Date of documentation and version number for open as well as for the closed part | [ ]  | [ ]  | [ ]  |  |
|  | Divisibility of tablets | [ ]  | [ ]  | [ ]  |  |
| **1.7 Decision of Foreign Authorities** |
| **1.7.1 Responses to LoQ** | [ ]  | [ ]  | [ ]  |  |
|  | The List of Question must also be available (not only the responses) | [ ]  | [ ]  | [ ]  |  |
|  | All questions/responses from/to member states must also be included for DCP/MRP | [ ]  | [ ]  | [ ]  |  |
| **1.7.2 Assessment Report** | [ ]  | [ ]  | [ ]  |  |
|  | All assessment reports to all variations submitted after maa and before submission to Swissmedic must also be available (if applicable)🡪 If a country does not compile assessment report, a Art. 13 submission is not possible | [ ]  | [ ]  | [ ]  |  |
|  | Also assessment reports from DCP/MRP must be submitted | [ ]  | [ ]  | [ ]  |  |
| **1.7.3 Decision (EU/FDA/Other Foreign Authorities)** | [ ]  | [ ]  | [ ]  |  |
|  | Submission is also possible only with the opinion form the EMA, but the decision must be submitted later | [ ]  | [ ]  | [ ]  |  |
|  | Marketing Authorization | [ ]  | [ ]  | [ ]  |  |
| **1.7.6 Paragraph 13 Additional Documentation** | [ ]  | [ ]  | [ ]  |  |
|  | Tracking Table of the foreign MAA | [ ]  | [ ]  | [ ]  |  |
|  | Tracking Table of the foreign variations since the Marketing Authorisation | [ ]  | [ ]  | [ ]  |  |

**Additional/Separate documents and information needed for submission of products with known active substances submission in Switzerland**

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| --- |
| Swiss Module 1 |
|  | **Available?** |  |
|  | **YES** | **NO** | **N/A** | **Comment** |
| **1.0 Cover Letter** | [ ]  | [ ]  | [ ]  |  |
|  | For known APIs with bioequivalence trials: state the foreign comparator product | [ ]  | [ ]  | [ ]  |  |
| **1.2.2.14 Checklist Formal Control Application Authorisation Human Medicines** | [ ]  | [ ]  | [ ]  |  |
|  | Name of the product and address of the MAH / Marketing authorisation number / LOT and EXP / Supplier country / Supplier / Address: (wholesale / pharmacy) of the foreign comparator product | [ ]  | [ ]  | [ ]  |  |
| **1.5 Data of Bioavailability Studies** |
| **1.5.1 Swissmedic Bioequivalence Trial Information Form** | [ ]  | [ ]  | [ ]  |  |
|  | Alternatively, the information can be submitted in European format as described in the Guideline on the Investigation on Bioequivalence(<http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001278.jsp&mid>) | [ ]  | [ ]  | [ ]  |  |
| **1.5.2 Documents on the Reference Product** | [ ]  | [ ]  | [ ]  |  |
|  | Comparative *in-vitro* dissolution between the foreign comparator product and the Swiss Reference product (see Guideline above and Product-specific bioequivalence guidance)(<http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000625.jsp&mid=WC0b01ac0580848f74>) | [ ]  | [ ]  | [ ]  |  |
| **1.5.3 Confirmation of Identity of Submitted Product and Reference Product Used in the Bioequivalence Studies** | [ ]  | [ ]  | [ ]  |  |
|  | Tabulated summary of comparing the foreign comparator and the Swiss reference product (e.g. composition, appearance, photograph, diameter, thickness, weight, X-ray Diffraction). | [ ]  | [ ]  | [ ]  |  |

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| --- |
| Module 3/4/5 |
|  | The information provided in Modules 3, 4 and 5 should reflect current state of the art knowledge according to the following guidelines:<http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000081.jsp&mid=WC0b01ac0580027546> | [ ]  | [ ]  | [ ]  |  |